PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

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PCT

REC'D 31 JUL 2006
WIPO PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Applicant's or agent's file reference 21085.0072P1	Date of mailing (*day/month/year*) 26 JUL 2006 FOR FURTHER ACTION See paragraph 2 below

International application No.	International filing date (*day/month/year*)	Priority date (*day/month/year*)
PCT/US05/07586	09 March 2005 (09.03.2005)	09 March 2004 (09.03.2004)

International Patent Classification (IPC) or both national classification and IPC

IPC: Please See Continuation Sheet
USPC: 424/677;514/886

Applicant

THE UAB RESEARCH FOUNDATION

1. This opinion contains indications relating to the following items:

- ☒ Box No. I — Basis of the opinion
- ☐ Box No. II — Priority
- ☐ Box No. III — Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV — Lack of unity of invention
- ☒ Box No. V — Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI — Certain documents cited
- ☐ Box No. VII — Certain defects in the international application
- ☐ Box No. VIII — Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(*b*) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US	Date of completion of this opinion	Authorized officer
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	29 June 2006 (29.06.2006)	JOHN PAK Telephone No. 571-272-1600

Form PCT/ISA/237 (cover sheet) (April 2005)

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Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:

☒ the international application in the language in which it was filed

☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ on paper

☐ in electronic form

c. time of filing/furnishing

☐ contained in the international application as filed.

☐ filed together with the international application in electronic form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

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Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has, within the applicable time limit:
   - ☐ paid additional fees
   - ☐ paid additional fees under protest and, where applicable, the protest fee
   - ☐ paid additional fees under protest but the applicable protest fee was not paid
   - ☒ not paid additional fees
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is
   - ☐ complied with
   - ☒ not complied with for the following reasons:

   See the lack of unity section of the International Search Report(Form PCT/ISA/210)

4. Consequently, this opinion has been established in respect of the following parts of the international application:
   - ☐ all parts.
   - ☒ the parts relating to claims Nos. 1-9 (to the extent they read on LiCl), 10, 13 (to the extent it reads on LiCl), 15-16 (to the extent they read on LiCl) and 17

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Box No. V Reasoned statement under Rule 43 *bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims NONE	YES
	Claims 1-10,13 and 15-17	NO
Inventive step (IS)	Claims NONE	YES
	Claims 1-10,13 and 15-17	NO
Industrial applicability (IA)	Claims 1-10,13 and 15-17	YES
	Claims NONE	NO

2. Citations and explanations:

Claims 1-10, 13 and 15-17 meet the criteria set out in PCT Article 33(4), and thus find industrial applicability because the subject matter claimed can be used for reducing the severity of inflammation in a subject.

Claims 1-10, 13 and 15-17 lack novelty under PCT Article 33(2) as being anticipated by WO 98/17288.

WO 98/17288 explicitly discloses administering lithium chloride over a period of 2-10 weeks to a human subject to combat human papilloma virus infection (see claims 5, 7, 9-11).

All of applicant's claim language are so imprecisely presented that they are all deemed to be anticipated by the cited prior art disclosure. Claims 2-3 require a 24 hour or 2 hour period before or after the subject is contacted with an inflammatory agent. This feature is most certainly met by any human subject, who is under constant exposure to various bacterial, viral and other inflammatory agents from ordinary environmental conditions. Thus, the method and subject in WO 98/17288, who has been treated with lithium chloride for 2-10 weeks, meet applicant's claims 2-3. Similarly, the 2 hour period before or after inflammation begins in claim 4 is also necessarily encompassed by the method and subject of WO 98/17288. Claims 5-9 recite various types of infections, but the subject of WO 98/17288 meets applicant's "subject with inflammation or at risk for inflammation" language. Claim 13 requires administration of LiCl prior to surgery, but since no time period prior to surgery is required, the method and subject in WO 98/17288 meet claim 13. Claims 15-16 recite specific mechanism by which LiCl inhibits GSK-3 activity, but since the subject in WO 98/17288 has been administered the same exact LiCl for 2-10 weeks, the same effect would necessarily be obtained in that subject.

For these reasons, claims 1-10, 13 and 15-17 lack novelty under PCT Article 33(2) as being anticipated by WO 98/17288.

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Supplemental Box
In case the space in any of the preceding boxes is not sufficient.

Continuation of IPC:
A61K 33/14(2006.01);A61P 29/00(2006.01)
A61P 31/00(2006.01),31/04(2006.01),31/20(2006.01)